



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,554	03/15/2006	Jeremy Marshall	30031171	9236
<div>465 7590 04/28/2008</div> <div>YOUNG & THOMPSON</div> <div>209 Madison Street</div> <div>Suite 500</div> <div>ALEXANDRIA, VA 22314</div>				
EXAMINER				
GETTMAN, CHRISTINA DANIELLE				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
04/28/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,554

Applicant(s)

MARSHALL ET AL.

Examiner

CHRISTINA D. GETTMAN

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the tip" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the exposed end" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the tip" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the forward free ends" in lines 15-16. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "abutment surfaces" in lines 16-17. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "said free ends" in line 18. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (U.S. Patent No. 4,527,561) in view of Rutynowski (U.S. Patent No. 2007/0135828). Burns disclose the invention substantially as claimed including a lancet (ref. 20) having a body (ref. 50) with a drive head (ref. 30) at one end and a projecting needle (ref. 44) at the other end, the body having a spring-like (ref. 28) feature projecting down both sides toward the location of the tip of the needle, the spring-like element being made from a flexible material, a casing (ref. 32) housing a lancet, a drive-spring (ref. 26) positioned between the end of the housing and the drive head of the lancet, the drive head of the lancet incorporating a flange (ref. 61) resting against a moveable rib (ref. 55) of the casing, a flexible button (ref. 60) on the casing, the forward free end of the spring-like element being spaced from the abutment surface in the casing (see space between ref. 28 and ref. 39), and the free ends engaging the abutment surface to compress the spring-like element (see Fig. 8). Burns does not disclose two undulating webs as the spring-like elements, the webs being out of phase with one another, a removable protective cap over the end of the needle, the cap linked to the free ends of the webs by a breakable connecting part, the cap provided with a head which located over flanges on the casing, or the webs and the body being from a single piece of material. Rutynowski teach two spring-like elements (ref. 13 and 14) located on each side of the body for the purpose of returning the body to the retracted position after the needle has punctured the skin. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have placed two

springs, as disclosed in Rutynowski, around the needle in order to push the penetrating tip back into the casing after penetration has occurred. Both Burns and Rutynowski disclose the use of compression webs (ref. 75 and ref. 11) to push an element in a desired position. Therefore, it would have been obvious to have used two web features on each side of the needle in order to push the needle back into the casing after penetration with equal force on each side of the needle. As is also shown by Rutynowski, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Burns with forming the body and webs from a single piece of material (see ref. 11 and ref. 6-8, Fig. 1) in order to reduce manufacturing costs. Rutynowski also teach the use of a cap (ref. 22) over the end of the needle for the purpose of shielding the distal end of the needle. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Burns with a protective cap, as taught by Rutynowski, in order to protect the distal end of the end from piercing extraneous material/tissue. Although Rutynoski is silent on how the protective cap is attached to the body, it is well-known to have breakable parts between a shield/cap and the protected element.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 4:30 pm (off every other Friday).

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina D Gettman/
Examiner, Art Unit 3734
571-272-3128

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731